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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,586	10/27/2003	Ekambar R. Kandimalla	HYB-005US5	3762

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EXAMINER	
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ART UNIT	PAPER NUMBER
1648	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/694,586	KANDIMALLA ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,21 and 41-51* is/are pending in the application.

4a) Of the above claim(s) *42-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-21, 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to communication filed 6/18/2008. The status of the claims is as follows: claims 20-21 and 41 are under current examination.

The following rejections have been withdrawn:

1. 35 USC 103 (Chaix and Schwartz)

Applicant provides that the teachings of Chaix and Schwartz do not relate to the claimed invention. While Chaix teaches an increase in nuclease resistance by inserting a 3'-3' linker in a sequence of different function than that of the claimed CpG-containing sequences, the ordinary artisan would not have predicted that the "accessibility of the 3' ends was not critical to immunostimulatory activity" (see REMARKS, page 7). This is found persuasive. According to the applied references, it would have only been obvious for the ordinary artisan to *try* and given a fundamental change in the oligonucleotide's structure, the artisan would not have been able to predict that the sequence would maintains its immunostimulatory function.

2. 35 USC 103 (Chaix, Schwartz, Smee and Schneider and Chait).

Applicant provides that the teachings of Smee as well as Schneider and Chait fail to provide a 7-deazaguanosine in the context of an immunostimulatory dinucleotide of formula CpG as claimed. The argument is persuasive. According to the teachings, there is no motivation to insert such an analog in this motif particularly because it would not have been predictable to the ordinary artisan that the CpG* would have maintained its functional role as an immunostimulatory dinucleotide as claimed given insertion of this analog would lead to altered structure of the oligonucleotide. The skilled artisan could

not have predicted, for example, that the CpG* would maintain its affinity to TLR's or lead to any specific immunostimulatory result following administration.

Double Patenting-MAINTAINED

These rejections are maintained and Applicant will address them as necessary at a later time. Note that Double Patenting rejection with copending Application No. 11/270805 has been withdrawn due to claim cancellations.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-21 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/174448. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of

claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends. Both sets of claims are drawn to 2'-deoxy-7-deazaguanosine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/234074. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/234075. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/174002. Although the conflicting claims are not

identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/173983. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends. Both sets of claims are drawn to 2'-deoxy-7-deazaguanosine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/173794. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends. Both sets of claims are drawn to 2'-deoxy-7-deazaguanosine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

claim 1 of copending Application No. 11/174282. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends. Both sets of claims are drawn to 2'-deoxy-7-deazaguanosine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/173938. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/174450. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends. Both sets of claims are drawn to 2'-deoxy-7-deazaguanosine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 5 of copending Application No. 10/757345. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends. Both sets of claims are drawn to 2'-deoxy-7-deazaguanosine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20-21 and 41 are rejected on the ground of nonstatutory double patenting over claims 1 and 3 of U. S. Patent No. 7276489 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends. Both sets of claims are drawn to 2'-deoxy-7-deazaguanosine.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Double Patenting-NEW

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-21 and 41 are rejected on the ground of nonstatutory double patenting over claims 1-3 of U. S. Patent No. 7105495 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends. Both sets of claims are drawn to 2'-deoxy-7-deazaguanosine.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of

the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 20-21 and 41 are rejected on the ground of nonstatutory double patenting over claim 1 of U. S. Patent No. 77115579 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends. Both sets of claims are drawn to 2'-deoxy-7-deazaguanosine.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 20-21 and 41 are rejected on the ground of nonstatutory double patenting over claims 1 of U. S. Patent No. 7176296 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends. Both sets of claims are drawn to 2'-deoxy-7-deazaguanosine.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 20-21 and 41 are rejected on the ground of nonstatutory double patenting over claims 1 and 3 of U. S. Patent No. 7276489 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends. Both sets of claims are drawn to 2'-deoxy-7-deazaguanosine.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 20-21 and 41 are rejected on the ground of nonstatutory double patenting over claims 1 and 6 of U. S. Patent No. 7407944 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends. Both sets of claims are drawn to 2'-deoxy-7-deazaguanosine.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 20, 21 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26 and 30 of copending Application No. 10/846167. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends. Both sets of claims are drawn to 2'-deoxy-7-deazaguanosine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20, 21 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18, 22-28, 30, 32 and 34 of copending Application No. 10/865245. Although the conflicting claims are not identical, they are not patentably distinct from each other

because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends. Both sets of claims are drawn to 2'-deoxy-7-deazaguanosine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20, 21 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-56 and 58-61 of copending Application No. 11/257769. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends. Both sets of claims are drawn to 2'-deoxy-7-deazaguanosine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20, 21 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 11/906781. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends. Both sets of claims are drawn to 2'-deoxy-7-deazaguanosine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20, 21 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

claims 14-21 of copending Application No. 11/876913. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends. Both sets of claims are drawn to 2'-deoxy-7-deazaguanosine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20, 21 and 41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 12/020694. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an oligonucleotide comprising a linker and two accessible 5' ends. Both sets of claims are drawn to 2'-deoxy-7-deazaguanosine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michelle Horning/
Examiner, Art Unit 1648
/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648